MINUTES OF
THE COMMITTEE ON THE PROTECTION OF THE RIGHTS OF HUMAN SUBJECTS
COMMITTEE C (3rd MONDAY)

MEETING: 1:00 P.M., Monday, December 17, 2001 Executive Board Room, Atrium, Lineberger Cancer Center

PRESENT: [redacted]

ABSENT WITHOUT ALTERNATE: [redacted]

CHAIR OF TODAY'S MEETING: [redacted]

STAFF: [redacted]

PREVIOUS MINUTES: The Committee voted to approve the Minutes of the November 19, 2001 meeting.

EXPEDITED REVIEWS: Descriptions of 47 submissions given expedited review [45 CFR 46.110] since the last convened meeting were received by the Committee. Of these, 3 were new studies, 29 were amendments and 15 were renewals.

EXEMPTIONS: Descriptions of 4 submissions that met the federal criteria for exemption [45 CFR 46.101] since the last convened meeting were received by the Committee.

FULL BOARD REVIEWS: The Committee reviewed 25 studies: 2 reconsiderations, 11 new, 3 amendments, and 9 renewals.

The following were **DISAPPROVED** for reasons detailed below and in a memo to the principal investigator. The investigator will be given the option of appealing the decision. Any appeals or resubmissions will be returned for consideration by the convened Committee.

[…INFORMATION NOT RELEVANT TO PROTOCOL # 01-PED-632 HAS BEEN REDACTED…]

The following were **DEFERRED** to allow investigators to provide further information or make substantive changes, as detailed below and in a memo to the principal investigator. Responses will be returned for consideration by the convened Committee.

[…INFORMATION NOT RELEVANT TO PROTOCOL # 01-PED-632 HAS BEEN REDACTED…]

(NEW) 01-PED-632 Characterization of Mucus and Mucins in Bronchoalveolar Lavage Fluids From Infants with Cystic Fibrosis (Terry L. Noah, M.D.)
motion for deferral: 9 for, 0 opposed, 0 abstained
The memo to the investigator states:

1) The primary concern of the Committee is that the protocol does not appear to offer any benefit to subjects yet represents more than a minor increase above minimal risk. In order to meet criteria for research in children under Code of Federal Regulations 45 CFR 46, Subpart D, the protocol must either hold out the prospect of "direct

benefit to the individual subjects" 46.405 or, if not providing benefit, then it must not represent more than a minor increase over minimal risk and provide information of "vital importance for the understanding or amelioration of the subject's disorder or condition", 46.406. Research not meeting either of these criteria can only be approved after submission to the Secretary of the Department of Health and Human Services, see 46.407 in Subpart D

2) Please see the enclosed marked consent for further recommended changes to be made prior to resubmission.

[…INFORMATION NOT RELEVANT TO PROTOCOL # 01-PED-632 HAS BEEN REDACTED…]